DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-288

Debio Recherche Pharmaceutique S.A.
c/o Target Research Associates
Attention: Robert J. McCormack
Vice President, Regulatory Affairs
554 Central Avenue
New Providence, NJ 07974

Dear Dr. McCormack:

Please refer to your new drug application (NDA) dated June 29, 2000, received June 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trelstar™ LA 11.25 mg (triptorelin pamoate for injectable suspension) .

We acknowledge receipt of your submissions dated July 12, August 17, 23, September 5, 7, October 4, 24, and December 5, 2000, January 25, 29, February 2, 5 (2), March 5, April 6, 27, May 14 (2), 21, June 1 (2), 7, 19 (2), 21, 25, 27, 28 and 29, 2001.

This new drug application provides for the use of Trelstar™ LA 11.25 mg (triptorelin pamoate for injectable suspension) for the palliative treatment of advanced prostate cancer.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted June 29, 2001, immediate container and carton labels submitted June 21, 2001). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21288." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your June 22, 2001, postmarketing study commitment, in your submission dated June 25, 2001. We also refer to the teleconference minutes dated June 21, 2001, in which the request to conduct a postmarketing study was discussed. This commitment is listed below.

Collect additional data concerning post-dosing testosterone levels in subjects treated with the 84-day formulation of triptorelin. Conduct an open-label study in which 15-20 patients will receive 3 doses Trelstar™ LA 11.25 mg (triptorelin pamoate for injectable suspension). Obtain blood samples for the measurement of serum testosterone at the time of screening, immediately prior to and 48 to 72 hours after the second and third dosed of Trelstar™ LA. Entry criteria should include a screening testosterone level > 5nmol/L.

Protocol Submission:	Within 2 months of the date of this letter
Study Start:	Within 7 months of the date of this letter
Final Report Submission:	Within 15 months of the start of the study

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jeanine Best, M.S.N., R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Susan Allen, M.D., M.P.H.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure